IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)	
	)	
L. Di Costanzo	)	Group Art Unit: 1618
	)	
Application No.: 09/914,544	)	Examiner: P.W. Dickinson
	)	
Filed: March 19, 2002	)	Confirmation No.:
	)	
For: Orally Dispersible Tablet with Low Friability and Method For Producing Same	)	
	)	

DECLARATION OF PASCAL OURY

I, Pascal OURY, do hereby state as follows:

1. I am submitting this Declaration in support of the above-referenced U.S. patent application no. 09/914,544.

2. I am the Head of Pharmaceutical Development of Ethypharm, the assignee of the referenced application. I have held that position since 1991. In that position, my responsibilities include supervising pharmaceutical development, manufacturing of clinical and regulatory batches, analytical development, scale-up efforts, industrialization, and process validation studies.

3. I hold a Doctorate in Pharmacy (1982); and a Masters Degree in Pharmacokinetics and Metabolism of Drugs (1983), both from Châtenay-Malabry, Paris XI University. A copy of my curriculum vitae is attached.

4. From 1981 to 1983, I was the acting resident at Creteil Hospital, Biochemistry and Pharmacology Department. My responsibilities included assaying drugs by enzyme-immunoassay and radio-immunoassay methods. From 1983 to 1985, I was quality control manager at Ethypharm. My responsibilities included conducting batch analyses and release studies. From 1985 to 1991, I was production manager at Ethypharm. My responsibilities included supervising the subcontracted manufacture of products derived from in-house development, as well as overseeing customer licenses.

5. I have extensive experience with drug delivery systems. Specifically, I have extensive experience with modified drug release forms, including prolonged release (delayed release, gastro-resistance, and site-specific delivery); immediate release oral forms (including bioavailability enhancement and taste-masking, including taste-masked pediatric suspensions); and prolonged release injectable forms (including PLAGA-based injectable microspheres). I also have extensive experience with polymeric particle coating processes and powder granulation and coating processes, as well as fast-disintegrating orodispersible tablets.

6. I am familiar with the specification of the referenced patent application. I have directed and supervised the preparation of orally dispersible tablets made in accordance with the methods of the referenced patent application. Attached are photomicrographs (by scanning electron microscopy) of coated microcrystals made in a manner consistent with that of example 1 of the referenced application. Figure 1A is a photomicrograph of uncoated paracetamol microcrystals; Figure 1B is a photomicrograph of paracetamol microcrystals with a continuous coating of polymer

produced by the method of example 1; and Figure 1C is a cross-section view of a coated paracetamol microcrystal made in accordance with the method of example 1. As in example 1, the microcrystals were coated with 10% by weight polymer relative to the total weight of the coated particles. The photomicrographs show a continuous layer of polymer coating the paracetamol microcrystals, and that the resulting polymer layer has a thickness of 10-70 µm. These properties are generally accepted within the field as effective for providing taste-masking properties. Based upon my many years of experience in pharmaceutical manufacturing generally, and coatings in particular, I conclude that the active agent microcrystals shown in those Figures have a continuous polymer coating, and that one of ordinary skill in the art reading the referenced specification and examples would have understood and expected that to have been the case.

7. I have considered US Patent No. 5,725,880, and particularly Example 3. One of ordinary skill in the art would have understood that a product resulting from the wet granulation method of Example 3 of the '880 patent would have been fundamentally different from the coated particles of the claims pending in this application. One of ordinary skill in the art would have understood that a wet granulation method would have produced a mixture of the various ingredients throughout the granule without any discrete or continuous coating as is seen in the microcrystals used in the claimed invention and as illustrated in Figures 1A-C.

8. I declare further that all statements made herein of my own knowledge are true, and all statements, made on information and belief, are believed to be true. Further, I am aware that any willful false statements and the like are punishable by

fine, imprisonment, or both (18 U.S.C. § 1001), and that such willful false statements may jeopardize the validity of any patent that may issue from the '262 application, and any patents and applications related thereto.

Sept. 1st 2009
Date

Pascal OURY